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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/951,832	10/16/1997	CESAR Z. LINA	VAC.312B.US	2039

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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
01/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/951,832	LINA ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-8,13,16-23,25 and 27-40* is/are pending in the application.

4a) Of the above claim(s) *13,16-21 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-8,22,23,25,27 and 31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 2, 2007 has been entered.

Response to Arguments

2. Applicant's arguments, see Remarks, filed November 2, 2007, with respect to the rejection(s) of claim(s) 3-8, 22, 23, 25 and 27 under 35 U.S.C. 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly found prior art references.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on November 2, 2007 was filed after the mailing date of the final action on August 9, 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The foreign references and non-patent literature documents were not considered, as applicant did not comply with the requirement of 37 C.F.R. 1.98 regarding providing a legible copy of each foreign reference and non-patent literature document.

The references cited by applicants in the IDS and listed on the numerous 1449's have been made of record. While the statements filed clearly do not comply with the guidelines set

forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material, rather they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references, however, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure, see Penn Yan Boats, inc. V. Sea Lark boats Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 3-8, 22, 23, 25, 27 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeil et al (U.S. Patent No. 4,710,165) in view of Kruger (U.S. Patent No. 4,743,232) and further in view of Cope et al (U.S. Patent No. 5,028,355).

With respect to **claim 8:** McNeil teaches a canister 22 for collecting fluids drawn through standard connecting tubes from a drainage site on a human, such as a wound via patient port 32 of collection canister 22. The canister 22 is fluidly connected with a second end of the standard connecting tube, which is opposite the first end of said tube located at the drainage site, via said port 32. Suction pump 10 applies negative pressure to said canister, and thus also said tube, said suction pump 10 being fluidly connected to said canister 22 via line 26. At least one bacterial filter 24 is positioned in line 26 between said canister 22 and said pump 10. A sensor in the form of a "full level" sensor detects when said canister 22 is substantially full with

fluid, said sensor being associated with said suction pump 10 via a logic circuit having an AND gate 124 that controls power to pump motor 80 to discontinue application of the negative pressure when a substantially full condition of said canister is detected. ('165, Col. 5, lines 1-31, 36-40, Col. 7, lines 52-57, Col. 8, lines 10-13)

McNeil does not teach an elastomeric dressing. Kruger teaches an elastomeric dressing 10 comprising a polyether polyamide elastomer material and a tube 20 in fluid communication with the elastomeric film dressing 10. The dressing 10 has a pressure sensitive acrylic adhesive 14 in at least the peripheral areas and is inherently and necessarily capable of securing a porous pad thereunder to the tissue within a sealed space defined by the inner surface of the film dressing 10. Thus, the tube 20, which extends under the wound-facing surface of dressing 10, has a first end that would be in fluid communication with said porous pad via the dressing 10. ('232, Col. 3, lines 32-45, Col. 3, lines 53 – Col. 4, lines 7, Col. 4, lines 16-25)

Neither McNeil nor Kruger teaches a porous pad which is permeable to fluids. Cope teaches that polyether foams and the methods of forming them are known in the art. These foams are permeable to fluids and thus capable of use as a porous pad for wound fluid absorption. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of McNeil and Kruger so as to include a porous pad that is permeable to fluids to aid in absorption of wound exudates at the wound site. The combined teaching of McNeil and Kruger and Cope meets all of the limitations of claim 8 and thus is a therapeutic combination for promoting tissue healing. ('355, Col. 4, lines 65-68)

With respect to **claim 3:** McNeil teaches that the canister 22 can be mounted on the side or beneath the pump, therefore the canister 22 is considered herein to be removably attached to a

housing 10 for said pump.

With respect to **claim 4:** The canister 22 is removably received in a recess in the housing. (Fig. 1)

With respect to **claim 5:** Kruger teaches a tube 20 that is received in a bore 30 defined by plastic member 28 and continues through to below the wound-facing surface of dressing 10, where the porous pad would be located and is capable of being inserted into the porous pad, i.e. the tube is fitted as an interference fit into an interior portion of said porous pad, as an interference fit is interpreted herein as a fitting between two parts by friction alone.

With respect to **claim 6:** The pad of Cope comprises a polymer foam in the form of a polyether foam and has interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claims 7,23:** The foam of Cope is a polyether reticulated foam having a void volume of more than 90%, which is interpreted herein as meaning that the foam has at least 90% interconnecting cells, which overlaps the claimed range of at least 95% interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claim 22:** The foam of Cope is a polyether reticulated foam having a void volume of more than 90%, which is interpreted herein as meaning that the foam has at least

90% interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claim 25:** McNeil does not teach a tilt sensor for determining tilting of said device beyond a predetermined angle. However, McNeil does fairly suggest a tilt sensor by teaching a shut-off valve that closes off line 26 to the pump 10 if the canister 22 is tipped, which would necessarily require tipping the entire device and carrying case 16 as the canister 22 is inside the carrying case 16 during use. The shut-off valve is part of canister 22, which is associated with said suction pump 10 via line 26 and discontinues application of the negative pressure when tilting of said combination, i.e. the device, beyond said predetermined angle is detected. Thus it would be obvious to one of ordinary skill in the art to modify the device of McNeil such that the canister, and thus the device, further comprises a tilt sensor to aid in the operation of the shut-off valve in the event that the shut-off valve has not already shut off negative pressure in line 26.

With respect to **claim 27:** The peripheral areas of the dressing of Kruger with the pressure-sensitive adhesive would necessarily extend beyond the periphery of the porous pad of Cope for adhering to intact skin around the wound, as Kruger teaches that the adhesive must adhere to the skin directly.

With respect to **claim 31:** McNeil teaches a canister 22 for collecting fluids drawn through standard connecting tubes from a drainage site on a human, such as a wound via patient port 32 of collection canister 22. The canister 22 is fluidly connected with a second end of the standard connecting tube, which is opposite the first end of said tube located at the drainage

site, via said port 32. Suction pump 10 applies negative pressure to said canister, and thus also said tube, said suction pump 10 being fluidly connected to said canister 22 via line 26. At least one bacterial filter 24 is positioned in line 26 between said canister 22 and said pump 10. A sensor in the form of a "full level" sensor detects when said canister 22 is substantially full with fluid, said sensor being associated with said suction pump 10 via a logic circuit that controls power to pump motor 80 to discontinue application of the negative pressure when a substantially full condition of said canister is detected. ('165, Col. 5, lines 1-31, 36-40, Col. 7, lines 52-57, Col. 8, lines 10-13)

McNeil does not teach a tilt sensor for determining tilting of said combination beyond a predetermined angle. However, McNeil does fairly suggest a tilt sensor by teaching a shut-off valve that closes off line 26 to the pump 10 if the canister 22 is tipped, which would necessarily require tipping the entire device and carrying case 16 as the canister 22 is inside the carrying case 16 during use. The shut-off valve is part of canister 22, which is associated with said suction pump 10 via line 26 and discontinues application of the negative pressure when tilting of said combination, i.e. the device, beyond said predetermined angle is detected. Thus it would be obvious to one of ordinary skill in the art to modify the device of McNeil such that the canister, and thus the device, further comprises a tilt sensor to aid in the operation of the shut-off valve in the event that the shut-off valve has not already shut off negative pressure in line 26.

McNeil does not teach an elastomeric dressing. Kruger teaches an elastomeric dressing 10 comprising a polyether polyamide elastomer material and a tube 20 in fluid communication with the elastomeric film dressing 10. The dressing 10 has a pressure sensitive acrylic adhesive in all areas, and thus also peripheral areas, inherently and necessarily capable of securing a porous pad thereunder to the tissue within a sealed space defined by the inner surface of the film dressing 10. Thus, the tube 20, which extends under the wound-facing surface of dressing

10, has a first end that would be in fluid communication with said porous pad via the dressing 10. ('232, Col. 3, lines 32-45, Col. 3, lines 53 – Col. 4, lines 7, Col. 4, lines 16-25)

Neither McNeil nor Kruger teaches a porous pad which is permeable to fluids. Cope teaches that polyether foams and the methods of forming them are known in the art. These foams are permeable to fluids and thus capable of use as a porous pad for wound fluid absorption. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of McNeil and Kruger so as to include a porous pad that is permeable to fluids to aid in absorption of wound exudates at the wound site. The combined teaching of McNeil and Kruger and Cope meets all of the limitations of claim 31 and thus is a therapeutic combination for promoting tissue healing. ('355, Col. 4, lines 65-68)

With respect to **claim 32:** McNeil teaches that the canister 22 can be mounted on the side or beneath the pump, therefore the canister 22 is considered herein to be removably attached to a housing 10 for said pump.

With respect to **claim 33:** The canister 22 is removably received in a recess in the housing. (Fig. 1)

With respect to **claim 34:** Kruger teaches a tube 20 that is received in a bore 30 defined by plastic member 28 and continues through to below the wound-facing surface of dressing 10, where the porous pad would be located and is capable of being inserted into the porous pad, i.e. the tube is fitted as an interference fit into an interior portion of said porous pad, as an interference fit is interpreted herein as a fitting between two parts by friction alone.

With respect to **claim 35:** The pad of Cope comprises a polymer foam in the form of a polyether foam and has interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claims 36,38:** The pad of Cope is a polyether reticulated foam having a void volume of more than 90%, which is interpreted herein as meaning that the foam has at least 90% interconnecting cells, which overlaps the claimed range of at least 95% interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claim 37:** The foam of Cope is a polyether reticulated foam having a void volume of more than 90%, which is interpreted herein as meaning that the foam has at least 90% interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra* with respect to claim 8.

With respect to **claim 39:** The peripheral areas of the dressing of Kruger with the pressure-sensitive adhesive would necessarily extend beyond the periphery of the porous pad of Cope for adhering to intact skin around the wound, as Kruger teaches that the adhesive must adhere to the skin directly.

With respect to **claim 40:** McNeil teaches a canister 22 for collecting fluids drawn through standard connecting tubes from a drainage site on a human, such as a wound via patient port 32 of collection canister 22. The canister 22 is fluidly connected with a second end of the standard connecting tube, which is opposite the first end of said tube located at the drainage

site, via said port 32. Suction pump 10 applies negative pressure to said canister, and thus also said tube, said suction pump 10 being fluidly connected to said canister 22 via line 26. At least one bacterial filter 24 is positioned in line 26 between said canister 22 and said pump 10. A sensor in the form of a "full level" sensor detects when said canister 22 is substantially full with fluid, said sensor being associated with said suction pump 10 via a logic circuit that controls power to pump motor 80 to discontinue application of the negative pressure when a substantially full condition of said canister is detected. McNeil teaches that the canister 22 can be mounted on the side or beneath the pump, therefore the canister 22 is considered herein to be removably attached to a housing 10 for said pump. The canister 22 is removably received in a recess in the housing. ('165, Fig. 1, Col. 5, lines 1-31, 36-40, Col. 7, lines 52-57, Col. 8, lines 10-13)

McNeil does not teach a tilt sensor for determining tilting of said combination beyond a predetermined angle. However, McNeil does fairly suggest a tilt sensor by teaching a shut-off valve that closes off line 26 to the pump 10 if the canister 22 is tipped, which would necessarily require tipping the entire device and carrying case 16 as the canister 22 is inside the carrying case 16 during use. The shut-off valve is part of canister 22, which is associated with said suction pump 10 via line 26 and discontinues application of the negative pressure when tilting of said combination, i.e. the device, beyond said predetermined angle is detected. Thus it would be obvious to one of ordinary skill in the art to modify the device of McNeil such that the canister, and thus the device, further comprises a tilt sensor to aid in the operation of the shut-off valve in the event that the shut-off valve has not already shut off negative pressure in line 26.

McNeil does not teach an elastomeric dressing. Kruger teaches an elastomeric dressing 10 comprising a polyether polyamide elastomer material and a tube 20 in fluid communication with the elastomeric film dressing 10. The dressing 10 has a pressure sensitive acrylic adhesive

in all areas, and thus also peripheral areas, inherently and necessarily capable of securing a porous pad thereunder to the tissue within a sealed space defined by the inner surface of the film dressing 10. Thus, the tube 20, which extends under the wound-facing surface of dressing 10, has a first end that would be in fluid communication with said porous pad via the dressing 10. ('232, Col. 3, lines 32-45, Col. 3, lines 53 – Col. 4, lines 7, Col. 4, lines 16-25)

Neither McNeil nor Kruger teaches a porous pad which is permeable to fluids. Cope teaches that polyether foams and the methods of forming them are known in the art. These foams are permeable to fluids and thus capable of use as a porous pad for wound fluid absorption. Therefore it would be obvious to one of ordinary skill in the art to modify the device of the combined teaching of McNeil and Kruger so as to include a porous pad that is permeable to fluids to aid in absorption of wound exudates at the wound site. The combined teaching of McNeil and Kruger and Cope meets all of the limitations of claim 40 and thus is a therapeutic combination for promoting tissue healing.

The foam of Cope is a polyether reticulated foam having a void volume of more than 90%, which is interpreted herein as meaning that the foam has at least 90% interconnecting cells. The motivation to combine the teachings of McNeil and Kruger and Cope is stated *supra*. The peripheral areas of the dressing of Kruger with the pressure-sensitive adhesive would necessarily extend beyond the periphery of the porous pad of Cope for adhering to intact skin around the wound, as Kruger teaches that the adhesive must adhere to the skin directly. ('355, Col. 4, lines 65-68)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 9, 2008

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER